

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the remarks that follow.

Claim 4 is amended to incorporate the subject matter of claim 30 and specifically recite the lupeol content of the lupeol rich extract. Accordingly, claim 30 is now cancelled. Claims 1-3, 5 and 11-25 were previously cancelled.

No new matter has been added. Support for the amendment is found in original claim 30 and on page 12, lines 24-29, of the English translation of the specification.

I. INFORMATION DISCLOSURE STATEMENT (IDS)

The PTO indicates that the information disclosure statement filed August 10, 2010, did not include the appropriate fee. Office action, page 2. Applicants have concurrently herewith filed an IDS resubmitting WO 98/4749 and FR 2778565 for consideration. Applicants request the PTO to initial and return the attached form PTO/SB/08.

II. INDEFINITENESS REJECTIONS

The PTO states that claims 4, 6-10 and 33-34 are indefinite in view of the phrase “lupeol-rich extract.” The PTO states that multiple definitions for the objected term are provided in the specification, and it is not clear, therefore, which term limits the objected phrase.

Applicants traverse this rejection. To further prosecution, however, Applicants have amended claim 4 to recite an amount for the lupeol content of the lupeol rich extract. Accordingly, the rejection is moot.

III. OBVIOUSNESS REJECTION

Claims 4, 6, 9-10 and 30-34 are rejected as being unpatentable over Msika et al. (US 6,146,616), in view of Murad (US 5,972,999). More specifically, the PTO states that Applicants’ previous response states in one instance that Msika’s lupine oil does not contain lupeol, while in a second instance the response refers to Msika’s Example 1 and the

accompanying Table 1 to disclose a 0.1-1.0 wt% of lupeol in the disclosed lupine oil. Office action, page 5. Stating that both arguments cannot be correct, the PTO asserts that Msika's teaching of lupine oil having lupeol renders unpatentable the claimed invention.

Applicants respectfully disagree.

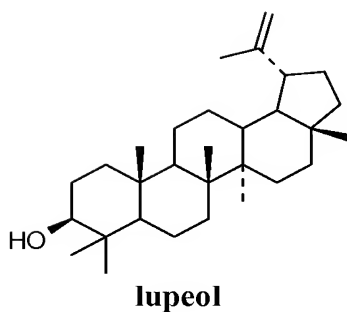
The rejection is moot as applied to now cancelled claim 30. The obviousness rejection is further discussed below as it may apply to the remaining claims.

Claim 4 is amended to recite a method for improving cicatrisation process, for restructuring the skin and/or the mucous membranes, for treating the sagging of the skin and/or the mucous membranes comprising administering to a patient in need thereof a lupeol-rich extract having a lupeol content greater than 30% by weight. As set forth in amended claim 4, the lupeol-rich extract is obtained from Pods of lupin and the inventive composition comprises between 0.0003% to 10% by weight lupeol.

In contrast, Msika discloses an antioxidant and anti-elastase composition containing lupine oil. Msika teaches that its antielastase composition contains lupine oil or one or more fractions thereof. See col. 1, lines 60-63. According to Msika, the lupine oil is extracted from lupine meals and/or seeds, particularly by direct pressing of lupine seeds. See col. 1, lines 63-65. Msika further teaches that "lupine oil has a particularly high content of polyphenol, β -carotene" and that the disclosed antioxidant and/or antielastase properties of the composition are due to the presence of polyphenol derivatives extracted from lupine oil." See col. 2, lines 19-28.

The PTO contends that Msika's disclosed composition should contain lupeol. See page 5 of the Office Action.

As disclosed in the present specification, however, **lupeol is not a phenol or phenol derivative**. Rather, as illustrated by the structure of lupeol (below), it is readily apparent that lupeol **does not** contain a phenolic moiety, but is a polycyclic fused ring system having an alcohol group (reproduced from paragraph [0003] of the published application):



The examiner has relied on working example 1 in Msika to teach extraction of crude lupine oil having a lupeol content of between 0.1-1% lupeol from lupine seeds. Applicants note, however, that Msika's disclosed protocol for extracting lupine oil requires decortication of seeds, that is, removal of pods from seeds, prior to extraction of the lupine oil. (See col. 4, lines 10-12.). Msika does not teach or suggest a composition comprising a lupeol-rich extract obtained from **lupine pods**.

No reading of Msika would have indicated to the skilled artisan to formulate a composition in which the lupeol rich extract obtained from lupine pods as claimed. In fact, lupine oil obtained from decorticated seeds would contain a much lower lupeol content than crude oil extracts obtained using the entire seeds. Furthermore, based on Msika's disclosure there is no reason to believe that the disclosed extraction protocol reproducibly provided the stated amount of lupeol. That is, Msika's composition could well have contained variable trace amounts of lupeol depending on the extraction process used. Msika's lupine oil composition, therefore, would not be understood by the skilled artisan to contain a lupeol-rich extract having between 0.0003% to 10% by weight lupeol as claimed.

Moreover, it is readily apparent that Msika's focus is on providing a cosmetic composition that provides suitable protection against harmful UVA and/or UVB radiation, or can be used as a restructuring or toning cream, an antiwrinkle cream, or a protective day cream (Co1. 3, lines 17-25). The skilled artisan cognizant of Msika's teachings, moreover, would readily have known that the stated beneficial effects of the disclosed composition, namely, the anti-elastase and antioxidant properties stem from the presence of polyphenol derivatives found in lupin oil. That is, Msika does not teach or even suggest the that the displayed anti-wrinkle/anti-oxidative effects are from lupeol.

In sharp contrast, the inventive composition containing a lupeol-rich extract stimulates expression of heat shock proteins, more particularly, expression of heat shock protein 47 in human skin fibroblasts. As set forth in the specification and working examples 2 and 3, the inventive composition stimulates metabolism and proliferation of fibroblasts. The claimed composition also influence collagen production and have a demonstrable beneficial effect on normal fibroblasts and stretch mark fibroblasts (see example 4).

These findings are unexpected because Msika attributes the beneficial effects of lupin oil to the presence of polyphenol derivatives, with no teaching for stimulation of heat-shock proteins due to lupeol. Furthermore, there is no reason to believe that Msika's teachings regarding the antielastase properties of the disclosed composition provide any guidance so as to allow the skilled artisan to arrive at the inventive method for improving cicatrization, or for restructuring skin, or mucous membranes and for treating the sagging of the skin.

Murad is cited in the Office action as a secondary reference. However, the Office action fails to discuss the teachings of Murad and why Murad would have been understood by the skilled artisan to remedy the deficiencies of Msika, so as to arrive at the claimed invention.

Applicants assume therefore, that Murad is being cited for its disclosure about the appearance of stretch marks on skin due to damage of the collagen and elastin proteins in skin. As such, Murad could not remedy, however, the deficiencies of Msika. Accordingly, the combination of Msika and Murad fail to defeat the patentability of the claimed invention.

Accordingly, Claim 4 is non-obvious over the cited references.

Dependent claims 7 and 8 are rejected over the combined teachings of Msika, Murad and the Hernandez-Perez technical article, or over the combined teachings of Msika, Murad and Herman (US 5,190, 979).

The Hernandez-Perez article is cited to teach stretch marks in pregnant women while Herman is cited to teach oral dosage in the form of a mouthwash. As stated above, the combination of Msika and Murad fail to defeat the patentability of independent claim 4

whose limitations are incorporated in dependent claims 7 and 8. The dependent claims are patentable, therefore, for at least the same reasons mentioned above for claim 4. The teachings of Hernandez-Perez and Herman do not remedy the deficiencies of Msika and Muard. Accordingly, they do not defeat patentability of claims 7 and 8.

In sum, Applicants maintain non-obviousness of the claims because:

- Msika does not teach or suggest the inventive method,
- Msika discloses that lupeol is extracted from lupine seeds after decortication, i.e., removal of pods, and
- The cited secondary references do not remedy the stated deficiencies in Msika.

Thus, all pending claims are patentable over the cited references, and Applicants respectfully request reconsideration and withdrawal of the section 103 rejection.

CONCLUSION

Having advanced credible remarks in support of patentability of the claimed invention, Applicant respectfully requests the Examiner to withdraw the rejections. Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned attorney if any issues remain in the present application.

Respectfully submitted,

Date 15-Apr-2011

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The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.